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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Mastrodonato and Braguti

Confirmation No.: 8421

Serial No.: 10/080,736

Art Unit: 1623

Filed: February 22, 2002

Examiner: Michael C. Henry

For: COMPOSITIONS AND METHODS FOR
THE TREATMENT OR PREVENTION OF
INFLAMMATION

Attorney Docket No: 11109-004

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INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & § 1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the continuing duty of disclosure imposed by 37 C.F.R. § 1.56 to inform the Patent and Trademark Office of all references coming to the attention of Applicants or Attorneys for Applicants which are or may be related to patentability of the claimed invention, Applicants hereby direct the Examiner's attention to references A01-A05, B01 and C01-C76 which are listed on the accompanying revised PTO Form 1449 entitled "List of References Cited by Applicant." A copy of each of References A01-A05, B01 and C01-C76 is submitted herewith.

Identification of the listed references is not to be construed an admission of Applicants or Attorneys for Applicants that such references are available as "prior art" against the subject application. Applicants respectfully request that the Examiner consider the foregoing references and that the references be made of record in the file of the above-captioned application.

Pursuant to 37 C.F.R. § 1.97, a fee of \$180.00 is believed to be due. Please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150. A duplicate of this sheet is enclosed for accounting purposes

Respectfully submitted,

Date: November 20, 2003

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LIST OF REFERENCES CITED BY APPLICANT
(Use several sheets if necessary)

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11109-004-999

APPLICATION NO

10/080,736

APPLICANT

Mastrodonato et al.

FILING DATE

February 22, 2002

GROUP

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U.S. PATENT DOCUMENTS

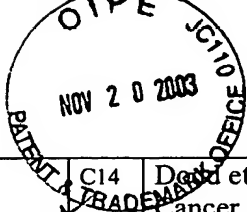
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A01	6,140,312	10/31/00	Falk et al.			
	A02	6,136,793	10/24/00	Falk et al.			
	A03	6,114,314	9/5/00	Falk et al.			
	A04	4,736,024	4/5/98	Della Valle et al.			
	A05	4,707,354	11/17/87	Garlen et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO
	✓B01	EP 0 444 492 B1	2/18/91	EPO			X

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

✓C01	Abatangelo et al., 1983, "Healing of hyaluronic acid-enriched wounds: histological observations," J. Surg. Res. 35(5):410-6
✓C02	Abatangelo, et al. 1997, "Hyaluronic acid delays or impedes reepithelialization?" J. Burn Care Rehabil. 18(6):552
✓C03	Akao, et al., 1992, "Inhibitory Effects of Glycyrrhetic Acid and Its Related Compounds on 3 α -Hydroxysteroid Dehydrogenase of Rat Liver Cytosol," Chem. Pharm. Bull. (Tokyo), 40(5):1208-1210
✓C04	Allen, L.V. Jr., Contemporary compounding: Products for stomatitis, U.S. Pharmacist 1990;8, pp. 88-90.
✓C05	Bao, et al., 1997, "Effect of sodium glycyrrhetinate on chemical peritonitis in rats," Chung Kuo Yao Li Hsueh Pao, 18(3): 277-280
✓C06	Barker, 1999, "Current practices in the oral management of the patient undergoing chemotherapy or bone marrow transplantation," Support Care Cancer 7(1):17-20
✓C07	Breast Cancer: Changing Diet and Fitness Questions and Answers downloaded from http://my.webmd.com
✓C08	Burgess, et al., 1990, "Pharmacological management of recurrent oral mucosal ulceration," Drugs 39(1):54-65
✓C09	Cantelli-Forti, et al., 1997, "Toxicological assessment of liquorice: biliary excretion in rats," Pharmacol. Res. 35(5):463-70
✓C10	Carrington Oral Wound Rinse for Oral Mucosa http://www.carringtonlabs.com
✓C11	Carrington Laboratories/Caraloe Product Ingredients, Radiacare Oral Wound Rinse.
✓C12	Commentary, 1991, "Oral complications of cancer therapies: diagnosis, prevention, and treatment," The National Institutes of Health Consensus Development Conference Statement, Oncology (Huntingt). 5(7):64, 69-76, 79 passim.
✓C13	Diary from a Week in Practice dated Dec. 1, 2001 downloaded from www.aafp.org



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TECH CENTER 16

✓ C14	Dodd et al., 1996, "Comparison of methods to determine the prevalence and nature of oral mucositis," Cancer Pract. 4(6):312-8
✓ C15	Dodd, 2001, "A comparison of the affective state and quality of life of chemotherapy patients who do and do not develop chemotherapy-induced oral mucositis," J. Pain Symptom Manage. 21(6):498-505
✓ C16	Dodds, et al., 1997, "Cortisol metabolism and its inhibition by glycyrrhetic acid in the isolated perfused human placental lobule," J. Steroid Biochem. Mol. Biol. 62(4):337-43
✓ C17	Eilers et al., 1988, "Development, testing, and application of the oral assessment guide," Oncol. Nurs. Forum. 15(3):325-30
✓ C18	Fain Gel: For Vaginal Mucosa http://www.elder-group.com/faingel.html
✓ C19	Ferrari et al., 2001, "In vivo 11beta-HSD-2 activity: variability, salt-sensitivity, and effect of licorice," Hypertension 38(6):1330-6
✓ C20	Fujisawa, et al., 2000, "Glycyrrhizin inhibits the lytic pathway of complement--possible mechanism of its anti-inflammatory effect on liver cells in viral hepatitis," Microbiol. Immunol. 44(9):799-804
✓ C21	Fujiwara, et al., 1983, "Hypokalemia and Sodium Retention in Patients with Diabetes and Chronic Hepatitis Receiving Insulin and Glycyrrhizin," Endocrinol. Japan 20(2):243-249
✓ C22	Glick, et al., 1992, "Alternative therapies for major aphthous ulcers in AIDS patients," J. Am. Dent. Assoc. 123(7):61-5
✓ C23	Gupta et al., 1994, "Interpolymer Complexation and its Effect on Bioadhesive Strength and Dissolution Characteristics of Buccal Drug Delivery Systems," Drug Development and Industrial Pharmacy, 20(3):315-325
✓ C24	Hanson, et al., 1997, "Protection from radiation-induced oral mucositis by a mouth rinse containing the prostaglandin E1 analog, misoprostol: a placebo-controlled, double-blind clinical trial," Advances in Experimental Medicine & Biology 400B:811-818
✓ C25	Heilmann, et al., 1999, "Administration of glycyrrhetic acid: significant correlation between serum levels and the cortisol/cortisone-ratio in serum and urine," Exp. Clin. Endocrinol. Diabetes 107(6):370-8
✓ C26	Hodgkin's Disease: Chemo downloaded from www.prism.gatech.edu
✓ C27	Inoue, et al., 1996, "Inhibitory effect of glycyrrhetic acid derivatives on capsaicin-induced ear edema in mice," Jpn. J. Pharmacol. 71(4):281-9
✓ C28	Jones, et al., 1998, "Viscoelastic properties of bioadhesive, chlorhexidine-containing semi-solids for topical application to the oropharynx," Pharm. Res. 15(7):1131-6
✓ C29	Jones, 1997, "Textural analysis and flow rheometry of novel, bioadhesive antimicrobial oral gels," Pharm. Res. 14(4):450-7
✓ C30	Jones, 1996, "Development and mechanical characterization of bioadhesive semi-solid, polymeric systems containing tetracycline for the treatment of periodontal diseases," Pharm. Res. 13(11):1734-8
✓ C31	Karthaus, et al., 1999, "Prophylaxis and treatment of chemo- and radiotherapy-induced oral mucositis - are there new strategies?" Bone Marrow Transplant. 24(10):1095-108
✓ C32	Khaksa, et al., 1996, "Anti-inflammatory and anti-nociceptive activity of disodium glycyrrhetic acid hemiphthalate," Planta Med. 62(4):326-8
✓ C33	Larson et al., 1998, "The PRO-SELF Mouth Aware program: an effective approach for reducing chemotherapy-induced mucositis," Cancer Nurs. 21(4):263-8
✓ C34	LeVeque et al., 1992, "Clinical Evaluation of MG209, an Anesthetic, Film-Forming Agent for Relief from Painful Oral Ulcers Associated with Chemotherapy," J. Clin. Onc. 10(12):1964-1968
✓ C35	Magic Mouthwash downloaded from www.fpnotebook.com
✓ C36	"Magic Mouthwash Recipes" updated November 11, 1999.* Downloaded from what-me/hepc/magicmw.html .
✓ C37	Mauricio et al., 1997, "Identification of glycyrrhizin as a thrombin inhibitor," Biochem. Biophys. Res. Commun. 235(1):259-63
✓ C38	McCarthy et al., 1998, "Risk factors associated with mucositis in cancer patients receiving 5-fluorouracil," Oral Oncol. 34(6):484-90
✓ C39	McGuire et al., 1993, "Patterns of mucositis and pain in patients receiving preparative chemotherapy and bone marrow transplantation," Oncol. Nurs. Forum. 20(10):1493-502
✓ C40	"Mouth Sores" dated January 12, 1997 downloaded from deltronix.com .

✓C41	Mueller, et al., 1995, "Mucositis management practices for hospitalized patients: national survey results," J. Pain Symptom Manage. 10(7):510-20
✓C42	Mueller, et al., 1995, "Pharmaceutical aspects of mucositis mouthwash mixtures," Am. J. Health Syst. Pharm. 52(22):2596-7
✓C43	Nagao, 1995, "A case of oral lichen planus with chronic hepatitis C successfully treated by glycyrrhizin," Kansenshogaku Zasshi 69(8):940-4
✓C44	North Carolina Board of Pharmacy, Frequently Asked Questions for Pharmacists downloaded from www.ncbop.org
✓C45	OraMagic: For Oral Mucosa http://www.fda.gov/cdrh/pdf2/k024180.pdf
✓C46	Paoletti, J. and McCord, K., Compounding Mouthwashes and Rinses for Oral Ulcerations, International Journal of Pharmaceutical Compounding, January/February 1999.
✓C47	Pico, et al., 1998, "Mucositis: Its Occurrence Consequences, and Treatment in the Oncology Setting," Oncologist 3(6):446-451
✓C48	Plasdone® Povidone USP Technical Profile, International Special Typroducts.
✓C49	Plevova et al., 1999, "Prevention and treatment of chemotherapy- and radiotherapy-induced oral mucositis: a review," Oral Oncol. 35(5):453-70
✓C50	Ploeger, et al., 2001, "The pharmacokinetics of glycyrrhizic acid evaluated by physiologically based pharmacokinetic modeling," Drug Metab. Rev. 33(2):125-47
✓C51	ProstaPotek: For Rectal Mucosa http://www.chronicprostatitis.com/algonot.html
✓C52	Quilitz, 1995, "Modulation of Chemotherapy-Induced Mucositis," Cancer Control 2(5):452-459
✓C53	Randomized clinical trial to treat oral mucositis in patients receiving chemotherapy, dated 1998. Downloaded from www.ons.org
✓C54	Ryu et al., 1999, "Increased bioavailability of propranolol in rats by retaining thermally gelling liquid suppositories in the rectum," J Control Release. 59(2):163-72
✓C55	Sanzgiri, et al., 1994, "Evaluation of mucoadhesive properties of hyaluronic acid benzyl esters," International Journal of Pharmaceutics (Netherlands), 107: 91-97
✓C56	Saxen et al., 1997, "Sustained relief of oral aphthous ulcer pain from topical diclofenac in hyaluronan: a randomized, double-blind clinical trial," Oral Surg. Oral Med. Oral Pathol. Oral Radiol. Endod. 84(4):356-61
✓C57	Serra, et al., 2002, "Glycyrrhetic acid decreases plasma potassium concentrations in patients with anuria," J. Am. Soc. Nephrol. 13(1):191-6
✓C58	Shibata, 2000, "A drug over the millennia: pharmacognosy, chemistry, and pharmacology of licorice," Yakugaku Zasshi. 120(10):849-62
✓C59	Shintani, et al., 1992, "Glycyrrhizin (Licorice)-Induced Hypokalemic Myopathy," Eur. Neurol. 32:44-51
✓C60	Sigurjonsdottir, 2001, "Licorice-induced rise in blood pressure: a linear dose-response relationship," J. Hum. Hypertens. 15(8):549-52
✓C61	Solomonidou, et al., 2001, "Effect of carbomer concentration and degree of neutralization on the mucoadhesive properties of polymer films," J. Biomater. Sci. Polym. Ed. 12(11):1191-205
✓C62	Stiff, P., 2001, "Mucositis associated with stem cell transplantation: current status and innovative approaches to management," Bone Marrow Transplant. 27 Suppl 2:S3-S11
✓C63	Tips for Giving Medicine That is Hard to Give (Copyright dates from 1997-2000)
✓C64	Van Rossum, et al., 2001, "'Pseudo-aldosteronism' induced by intravenous glycyrrhizin treatment of chronic hepatitis C patients," Journal of Gastroenterology and Hepatology 16(7):789-795
✓C65	Walgreens Kaopectate Children's Anti-diarrheal Liquid Cherry flavor Product Description downloaded from www.walgreens.com.
✓C66	Walgreens Kaopectate Concentrated Anti-Diarrheal Peppermint Flavor Product Description downloaded from www.walgreens.com.
✓C67	Walgreens Kaopectate Concentrated Anti-diarrheal regular flavor Product Description downloaded from www.walgreens.com.
✓C68	Walgreens Maalox Antacid Product Description downloaded from www.walgreens.com.

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 Sheet 4 of 4
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✓ C69	Walker, et al., 1995, "Endogenous inhibitors of 11 beta-hydroxysteroid dehydrogenase in hypertension," J. Clin. Endocrinol. Metab. 80(2):529-33
✓ C70	Walker, et al., 1994, "Licorice-induced hypertension and syndromes of apparent mineralocorticoid excess," Endocrinol. Metab. Clin. North Am. 23(2):359-77
✓ C71	Wang, et al., 2001, "Licorice and cancer," Nutr. Cancer. 39(1):1-11
✓ C72	Wilkes, 1998, "Prevention and treatment of oral mucositis following cancer chemotherapy," Semin. Oncol. 25(5):538-51
✓ C73	Wojtaszek, C., 2000, "Management of chemotherapy-induced stomatitis," Clin. J. Oncol. Nurs. 4(6):263-70
✓ C74	Woo, et al., 1996, "Recurrent aphthous ulcers: a review of diagnosis and treatment," J. Am. Dent. Assoc. 127(8):1202-13
✓ C75	Yamamura, et al., 1995, "The Relationship Between Pharmacokinetic Behaviour of Glycyrrhizin and Hepatic Function in Patients with Acute Hepatitis and Liver Cirrhosis," Biopharmaceutics and Drug Disposition 15:13-21
✓ C76	Yamamura, et al., 1992, "Pharmacokinetic profile of glycyrrhizin in healthy volunteers by a new high-performance liquid chromatographic method," J. Pharm. Sci. 81(10):1042-6

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